Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	October 12, 2004
Trade Name:	*NexGen*® Complete Knee Solution LPS-Flex *Prolong*™ Highly Crosslinked Polyethylene Articular Surfaces
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/ polymer semi-constrained cemented prosthesis 21 CFR § 888.3560 (JWH) Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR § 888.3565 (MBH)
Predicate Devices:	LPS-Flex Fixed Bearing Articular Surface Components, manufactured by Zimmer, Inc., K991581, cleared July 30, 1999. *Prolong* Highly Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Components, manufactured by Zimmer, Inc., K013991, cleared December 27, 2001. *NexGen* Porous, Uncemented Femoral and Tibial Baseplate Components, manufactured by Zimmer, Inc., K031061, cleared October 9, 2003.
Device Description:	The *NexGen* LPS-Flex *Prolong* articular surfaces are part of the NexGen system of semiconstrained, nonlinked condylar knee prostheses.

Intended Use:

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The device is indicated for use when both cruciate ligaments have been excised.
The device is intended for use as part of a cemented or uncemented knee prosthesis.

Comparison to Predicate Device:

Except for a change in material and minor dimensional modifications, LPS-Flex *Prolong* articular surfaces are identical to the predicate device. The modifications do not change the intended use or the fundamental scientific technology. The device is packaged using the same materials and processes.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Performance testing completed as part of the design assurance process demonstrated that this device is safe and effective and substantially equivalent to the predicate device.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2004

Mr. Brandon Hipsher
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K042271
Trade/Device Name: NexGen® Complete Knee Solution LPS-Flex Prolong™ Highly Crosslinked Polyethylene Articular Surfaces
Regulation Number: 21 CFR 888.3560 and 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis and Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JWH and MBH
Dated: September 10, 2004
Received: September 13, 2004

Dear Mr. Hipsher

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042271

Device Name:

NexGen® Complete Knee Solution LPS-Flex *Prolong*™ Highly Crosslinked Polyethylene Articular Surfaces

Indications for Use:

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042271